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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,085	01/16/2004	Hubert Koster	3800014.00025 / 2309	8019
77202	7590	07/07/2010		
K&L Gates LLP 3580 Carmel Mountain Road Suite 200 San Diego, CA 92130			EXAMINER GROSS, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1639	
			MAIL DATE	DELIVERY MODE
			07/07/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/760,085	<b>Applicant(s)</b> KOSTER ET AL.	
	<b>Examiner</b> CHRISTOPHER M. GROSS	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 6, 10, 15, 25, 34, 38, 43, 44, 75, 110, 116, 137, 139, 140, 144, 151, 152, 160-161, 163, 164, 166, 169, 175 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are  
1,2,5,6,10,15,17,18,22,25,34,38,43,44,47,55,56,63,66-68,75,77,110,116,137,139,140,143-147,151-  
153,155,156,160,161,163,164,166-169,171,172 and 175.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,17,18,22,46,47,55,56,63,66-68,77,143,145-  
147,153,155,156,167,168,171 and 172.

### **DETAILED ACTION**

The examiner tasked with the present application has again changed. See contact information below.

Responsive to communications entered 4/23/2010. Currently, claims 1, 2, 5, 6, 10, 15, 17, 18, 22, 25, 34, 38, 43, 44, 47, 55, 56, 63, 66-68, 75, 77, 110, 116, 137, 139, 140, 143-147, 151-153, 155-156, 160-161, 163-164, 166-169, 171-172 and 175 are pending. Claims 5, 17, 18, 22, 46, 47, 55, 56, 63, 66-68, 77, 143, 145-147, 153, 155, 156, 167, 168, 171, 172 stand withdrawn. Claims 1, 2, 6, 10, 15, 25, 34, 38, 43, 44, 75, 110, 116, 137, 139, 140, 144, 151, 152, 160-161, 163, 164, 166, 169, 175 are subject to the present restriction requirement.

The following election of species has been necessitated by applicant's amendment to the claims entered 4/23/2010 therein introducing species previously not considered.

### ***Election/Restrictions***

The examiner notes claims 41 and 174 are indicated as cancelled in the claim set pending presented 4/23/2010, whereas the p 12 of the remarks indicates 41 and 174 as pending. Page 12 of the remarks also does *not* list new claim 175 as pending. The basis for this office action is the status identifiers of the claim set. If applicant desires otherwise, a new claim set is required.

### ***Response to Arguments***

On pp 15-16 of the 4/23/2010 applicant argues: claim 17 should have not been withdrawn previously because applicants election of compound A on p 124 of the present specification as the species of capture compound bears Z as an amino acid which is not cleavable prior to or during mass spectrometric analysis and (ii) claim 5 should not have been withdrawn previously because it would have been impossible,

applicant asserts, for applicant to elect a single species which provides Y (e.g. drug) linked to Z “cores” in different orientations via different points of attachment on Y.

Applicant's arguments have been considered but are not deemed persuasive for the following reasons.

The following comments are made to address applicant's concerns despite the previous restriction requirement mailed 12/21/2005 was made FINAL in the office action mailed 11/15/2007.

(i) The Z core of compound A is not an amino acid, but rather a small dipeptide composed of 6-aminohexanoic acid connected to lysine through an amide bond involving the epsilon amine. In this vein, not only may peptides be cleaved (prior to mass spectrometry) by methods such as acid hydrolysis, but, solely to rebut applicant's argument, evidence in column 14 lines 16-21 of US 6797523 to Awrey et al indicates amide bonds in peptides are also fragmented during mass spectrometry. Therefore, Z in compound A being a dipeptide would be expected to be cleavable prior to - as well as - fragment during mass spectrometric analysis and thus compound A does not read on claim 17, but *does* read on claim 15 (drawn to cleavable Z).

(ii) In response to applicant's contention that it would have not been possible to elect a single species which fulfills the criteria set forth in claim 5, the examiner notes that p 70 of the specification recites dendrimeric Z cores as possibilities, which certainly would have provided a multitude of functional groups to which drug Y in different orientations could be attached, reading on claim 5. While the examiner appreciates applicant's regret in electing A bearing non-dendrimeric Z core, claim 5, unfortunately

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does not read on compound A. Furthermore it is noted the Z core now presented, in base claim 1 being only trifunctional appears to exclude dendrimers.

***Markush Group Member (Species) Election***

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Each **genus** identified below is indicated in **bold**.

(i) From claims 1,6,44,140,152,175,: Applicant is to elect a species of **X** **photoactivatable group** specified as to atom and bond. Currently claims 1,6,34,44,139,140,152,175 are generic.

The Markush group members are independent and/or distinct because the members have distinct and/or independent physiochemical properties that are mutually exclusive and therefore are not considered obvious variants of each other, such as excitation wavelength and stability in aqueous solution.

In addition, these species are not obvious variants of each other based on the current record.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

The species require a different fields of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries);

The prior art applicable to one species would not likely be applicable to another species;

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The species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

(ii) From claims 1 and 2 : Applicant is to elect a species of **Q sorting function for immobilization** selected from the group set forth in claim 2. Claims 1 and 2 are generic.

The Markush group members are independent and/or distinct because the members have distinct and/or independent chemical, physical, and biological structures and/or features and/or functions that are mutually exclusive and therefore are not considered obvious variants of each other. For example, Hexahistidine tags are purified by Nickel chelate chromatography, which is not possible with other members of the group in claim 2.

In addition, these species are not obvious variants of each other based on the current record.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

The species require a different fields of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries);

The prior art applicable to one species would not likely be applicable to another species;

The species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

(i) From claims 1,6,43,44,139,140,175: Applicant is to elect a species of **Z trifunctional amino acid** selected from the group consisting of serine, threonine,

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lysine, tyrosine, glutamate, aspartic acid and cysteine. Currently claims 1,6,34,43,44,137,139,140,175, are generic.

The Markush group members are independent and/or distinct because the members have distinct and/or independent physiochemical properties that are mutually exclusive and therefore are not considered obvious variants of each other. For example: the soft sulfur nucleophile of cysteine reacts with maleimides and the hard amine nucleophile of lysine reacts with N-hydroxysuccinates but not vice versa; unlike the other amino acids, tyrosine has a 254 nm UV absorption; finally The pKas of each amino acid side chain differs giving each a unique reactivity profile as a function of pH.

In addition, these species are not obvious variants of each other based on the current record.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

The species require a different fields of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries);

The prior art applicable to one species would not likely be applicable to another species;

The species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument**



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that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

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